



August 21, 2025

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.  
% Todd Courtney  
Vice President, Anesthesia, Respiratory, Sleep & ENT Regulatory Affairs  
MCRA  
803 7th St NW  
Washington, District of Columbia 20001

Re: K251130

Trade/Device Name: Portable Oxygen Concentrator (JM-P50A)  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Portable Oxygen Generator  
Regulatory Class: Class II  
Product Code: CAW  
Dated: July 24, 2025  
Received: July 25, 2025

Dear Todd Courtney:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Bradley Q. Quinn -S**

Bradley Quinn  
Assistant Director  
DHT1C: Division of Anesthesia,  
Respiratory, and Sleep Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K251130

Device Name

Portable Oxygen Concentrator (JM-P50A)

Indications for Use (Describe)

The Jumao JM-P50A Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients (ages 22 and older) requiring respiratory therapy on a prescriptive basis. It may be used in the home or in professional healthcare facility.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## Section 5: 510(k) Summary

### 1. Applicant Information

|                                       |          |                                                      |
|---------------------------------------|----------|------------------------------------------------------|
| Establishment<br>Registration number: |          | 3014810929                                           |
| Name:                                 |          | Jiangsu Jumao X-Care Medical Equipment Co.,<br>Ltd.  |
| Address:                              |          | No.36 Danyan Road, Danyang, Jiangsu 212300,<br>China |
| Contact<br>Person                     | Name:    | Yu Yao                                               |
|                                       | Address: | No.36 Danyan Road, Danyang,Jiangsu<br>212300,China   |
|                                       | TEL:     | +86-511-86197666                                     |
|                                       | Email:   | 541640111@qq.com                                     |

### 2. Official correspondent information of the submission

|          |                                                            |
|----------|------------------------------------------------------------|
| Name:    | Todd Courtney                                              |
| Address: | 803 7 <sup>th</sup> St NW Washington, DC 20001             |
| TEL:     | (202)-552-5800                                             |
| Email:   | <a href="mailto:tcourtney@mcra.com">tcourtney@mcra.com</a> |

Date prepared: August 21, 2025

### 3. Device Information

Trade Name: Portable Oxygen Concentrator  
Model: JM-P50A  
Classification name: Generator, Oxygen, Portable  
Review panel: Anesthesiology  
Product code: CAW  
Regulation Class: II  
Regulation Number: 868.5440

#### 4. Predicate Device Information

***Primary predicate device:***

|                          |                                            |
|--------------------------|--------------------------------------------|
| 510(k) submitter/holder: | Inogen, Inc..                              |
| 510(K) Number:           | K230052                                    |
| Trade Name:              | Inogen Rove 6 Portable Oxygen Concentrator |
| Model:                   | INOGEN ROVE 6                              |
| Classification name:     | Generator, Oxygen, Portable                |
| Review panel:            | Anesthesiology                             |
| Product code:            | CAW                                        |
| Regulation Class:        | II                                         |
| Regulation Number:       | 868.5440                                   |

#### 5. Device description

Portable Oxygen Concentrator, model: JM-P50A is a portable oxygen generator that is intended to release oxygen for respiratory therapy by physical means (a molecular sieve). It supplies a pulsed high concentration of oxygen and is used with a nasal cannula (supplied separately) to channel oxygen from the concentrator to the patient. The JM-P50A is small, portable and may be used in the home or in a professional healthcare facility.

Portable Oxygen Concentrator, model: JM-P50A, uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an air tank. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function.

Portable Oxygen Concentrator, model: JM-P50A, can be used in the home or in a professional healthcare facility. Power options include 100 – 240 V (50- 60Hz) AC power supply, rechargeable battery packs.

Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Portable Oxygen Concentrator, model: JM-P50A, senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.

The portable oxygen concentrator consists of main unit, battery, power adapter and carry case. The main gas pathway of oxygen concentrator is composed of particle filter, particle filters, air compressor, molecular sieve beds, manifold valve, sensors, air tank.

## **6. Indications for Use**

The Jumao JM-P50A Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients (ages 22 and older) requiring respiratory therapy on a prescriptive basis. It may be used in the home or in a professional healthcare facility.

## 7. Summary of technological characteristics of device compared to the predicate devices

| SE Comparisons         | Subject device<br>(Portable Oxygen Concentrator,<br>model: JM-P50A)                                                                                                                                                                                                   | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model:<br>INOGEN ROVE 6)                                                                                                                                                | Discussion of difference                                                                                                                                                                                                                                                                                                                          |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 510K#                  | TBD                                                                                                                                                                                                                                                                   | K230052                                                                                                                                                                                                                                  | N/A                                                                                                                                                                                                                                                                                                                                               |
| Product Code           | CAW                                                                                                                                                                                                                                                                   | CAW                                                                                                                                                                                                                                      | Same                                                                                                                                                                                                                                                                                                                                              |
| CFR                    | 21 CFR 868.5440                                                                                                                                                                                                                                                       | 21 CFR 868.5440                                                                                                                                                                                                                          | Same                                                                                                                                                                                                                                                                                                                                              |
| Classification         | 2                                                                                                                                                                                                                                                                     | 2                                                                                                                                                                                                                                        | Same                                                                                                                                                                                                                                                                                                                                              |
| Indications<br>for Use | The Jumao JM-P50A Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients (ages 22 and older) requiring respiratory therapy on a prescriptive basis. It may be used in the home or in a professional healthcare facility. | The Inogen Rove 6 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in the home or a professional healthcare facility. | <p>Similar with the predicate device</p> <p>The used environment of subject device is within the predicate device, and both devices are used in either the home or a professional healthcare facility.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p> |

|                     |     |     |      |
|---------------------|-----|-----|------|
| <b>Prescriptive</b> | Yes | Yes | Same |
|---------------------|-----|-----|------|

| SE Comparisons                                  | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                            | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                      | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Fundamental scientific technology</b>        | <ul style="list-style-type: none"> <li>Breath detection technology</li> <li>Molecular Sieve/pressure swing adsorption technology</li> </ul> | <ul style="list-style-type: none"> <li>Breath detection technology</li> <li>Molecular Sieve/pressure swing adsorption technology</li> </ul> | Same                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Patient use (Population of intended use)</b> | Adult patients only. Prescription Required                                                                                                  | Adults only. Prescription Required (refer to user manual of predicate device)                                                               | <p>Same</p> <p>The intended patient of subject device is within the predicate device, and the subject device declare the age scope.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety.</p>                                                                                                                                                                           |
| <b>Mains isolation</b>                          | Remove the DC input cord from the device.                                                                                                   | Remove both the DC input cord from the device. as well as the battery pack.                                                                 | <p>Similar with the predicate device</p> <p>The mains isolation relates to the electrical safety of the device.</p> <p>Both subject device and predicate device can be mains isolation through remove the DC input cord of AC adapter form the device, and the subject device doesn't have External Battery Charger. As well as the subject device has been testing against ANSI AAMI ES60601-1 and the clause 8.11.1 of ANSI AAMI</p> |

| SE Comparisons    | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)   | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                         | Discussion of difference                                                                                                                                                                                                                                                                                                                                        |
|-------------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                   |                                                                    |                                                                                                                                                | <p>ES60601-1 test result show the Mains isolation of subject device is effective.</p> <p>Therefore, the difference of subject device with predicate device does not raise different questions of safety.</p>                                                                                                                                                    |
| Dimensions (size) | With 8-Core battery: 8.6" H, 3.5" W, 7.4" D (18.7 X 8.8 X 21.7 cm) | <p>With standard battery 7.2 x 3.3 x 8.1 in (18.2 x 8.3 x 20.7 cm)</p> <p>With extended battery: 7.2 x 3.3 x 9.0 in (18.2 x 8.3 x 22.9 cm)</p> | <p>Similar with the predicate device</p> <p>The size of the subject device is slightly larger than that of the predicate device, but its weight The size of the subject device is slightly larger, but it does not affect the portability of the product.</p> <p>Therefore, the difference of subject device with predicate device does not raise different</p> |

| SE Comparisons         | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                                                                             | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                | Discussion of difference                                                                                                                                                                                                                                                                                                                      |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                        |                                                                                                                                                                                                                                                                              |                                                                                                                                                                       | questions of safety and effectiveness.                                                                                                                                                                                                                                                                                                        |
| Weight                 | 4.76 lbs with 8-core battery                                                                                                                                                                                                                                                 | With standard battery: 4.8 pounds (2.2kg)<br>With extended battery: 5.8 pounds (2.6kg)                                                                                | Similar with the predicate device<br><br>The weight of subject device is less than that of the predicate device. The subject device is lighter, and it does not affect the portability of the product.<br><br>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness. |
| Battery type           | Lithium Ion                                                                                                                                                                                                                                                                  | Lithium Ion                                                                                                                                                           | Same                                                                                                                                                                                                                                                                                                                                          |
| User/Patient Interface | User interface panel                                                                                                                                                                                                                                                         | User interface panel                                                                                                                                                  | Same                                                                                                                                                                                                                                                                                                                                          |
|                        | LCD Display to convey information about operating status in numbers and symbols.                                                                                                                                                                                             | LCD Display to convey information about operating status in numbers and symbols.                                                                                      | Same                                                                                                                                                                                                                                                                                                                                          |
|                        | Alarm Indicator-yellow graphical simulation of an indicator light (border color of screen) flashes or constant with “Alarm/Warning” triangle symbol and error message on the User interface panel to indicate abnormal operating conditions in compliance with IEC 60601-1-8 | Alarm Indicator – yellow LED on UIP above “Alarm/Warning” triangle symbol that illuminates to indicate abnormal operating conditions in compliance with IEC 60601-1-8 | Similar with the predicate device.<br>The subject device adopted the border color on the LCD screen to indicate the alarm state.<br>Border color is yellow and                                                                                                                                                                                |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                         | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                 | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                |                                                                                                                                                                                                          |                                                                                                                        | <p>constant means the low alarm priority.</p> <p>Border color is yellow and flashing means the medium alarm priority.</p> <p>At the same the “Alarm/Warning” triangle symbol and error message show on the LCD screen when the alarm condition is trigger.</p> <p>The alarm Indicator has also been tested in accordance with IEC 60601-1-8 and the test result of clause 6.3.2.2 of IEC 60601-1-8 test report shows the visual alarm signals is positive.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p> |
|                | Breath detection notification - the 'Oxygen inhalation indicator light'(LED light) on both sides of the device's user interface panel turns green when a breath is detected, triggering an oxygen pulse. | Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered. | <p>Similar with the predicate device.</p> <p>Both subject device and predicate device have the</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                             | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                       | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                |                                                                                                                              |                                                                                                                              | <p>breath detection notification and the LED green turn green when a breath is detected, triggering an oxygen pulse. As well as, both subject device and predicate device can trigger the “No breath detected” alarm when there is no breath for 60s. The difference between the subject device and predicate device is the LED light shape.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p> |
|                | Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with IEC 60601-1-8  | Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with IEC 60601-1-8. | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                | Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator. | Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator. | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                                                                                                                                                 | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                                                                                                                                                                    | Discussion of difference                                                                                                                                                                                                                                                                                                                                                   |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | Sieve beds – Users shall send device to provider for sieve bed replacement. Sieve beds are replaceable by removing the screws, pulling the columns out through a screwdriver. The replacement columns were installed by pushing them in then screw them on. And the sieve beds are only replaceable by a trained person of your device provider. | Sieve beds – Users may send device to provider for sieve bed replacement, or users may replace sieves. Sieve beds are user replaceable by pulling the wire handle while depressing the retaining tab to pull the columns out. The replacement columns are installed by pushing them in until the retaining tab snaps into place.          | Similar with the predicate device<br>Both subject device and predicated device have replaceable sieve beds but in different method. But the sieve beds of subject device only replaceable by a trained person of the device provider.<br>Therefore, the difference of subject device with predicate device does not raise different questions of safety and effectiveness. |
|                | Particle Filter – Patient instructed to clean particle filters once per week.                                                                                                                                                                                                                                                                    | Particle Filter – Patient instructed to clean particle filters once per week.                                                                                                                                                                                                                                                             | Same                                                                                                                                                                                                                                                                                                                                                                       |
|                | User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description        | User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description | Same                                                                                                                                                                                                                                                                                                                                                                       |
|                | Optional accessories- Carrying Bag                                                                                                                                                                                                                                                                                                               | Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger                                                                                                                                                                                                                                                                | Similar with the predicate device.<br><br>The subject device only has carrying bag, and the use                                                                                                                                                                                                                                                                            |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A) | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                                            | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                |                                                                  |                                                                                                                                                                                                                   | <p>environment of subject device is limited within the home and professional healthcare facilities.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p>                                                                                                                                                                                                  |
|                | External Battery Charger (EBC) not available                     | <p>External Battery Charger (EBC) – Optional accessory. Independent battery charger that utilizes an AC/DC power supply. The EBC slides onto the Inogen Rove 6 battery to charge outside of the concentrator.</p> | <p>Different</p> <p>The subject device doesn't have External Battery Charger (EBC), but the battery of the subject device could be recharged through the adapter power supply. As well as the use environment of subject device is limited within the home and professional healthcare facilities.</p> <p>Therefore, the difference of subject device with predicate device does not raise different questions of safety and effectiveness.</p> |

| SE Comparisons              | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A) | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                  | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | No Mobile Application                                            | Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French. | <p>Different</p> <p>The subject device doesn't have mobile application, but the same information: device setting, battery information and current alerts is available on the LCD screen of subject device.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p>                                    |
| <b>Operating System</b>     | Software monitored                                               | Software monitored                                                                                                                                                                      | Same                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Bluetooth Technology</b> | Not available                                                    | <p>Inogen Connect App – BLE Connection to Android or iPhone.</p> <p>The Inogen Rove 6 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App.</p>        | <p>Different</p> <p>The subject device doesn't have mobile application or Bluetooth function. The following information is the same: device setting, battery information and current alerts is available on the LCD screen of subject device.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p> |

| SE Comparisons                | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                               | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                         | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Main technological components | Particle filters, air compressor, molecular sieve beds, manifold valve, sensors, air tank, battery                                                             | Particle filters, compressor, molecular sieve beds, manifolds and precision valves, sensors, accumulator reservoir, battery                                    | Same<br>Just in different words.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Components                    | AC/DC Power Adapter – Utilizes 100-240V, 50-60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator. | AC/DC Power Adapter – Utilizes 100-240V, 50-60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator. | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                               | NA                                                                                                                                                             | DC Power Cable – cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator.    | <p>Different</p> <p>The subject device does not come with a DC power cable. Instead, it is equipped with an AC adapter that can convert AC power to DC power for the device's power supply and battery charging.</p> <p>As well as the use environment of subject device is limited within the home and professional healthcare facilities, as well as it is without in transport environment to use.</p> <p>Therefore, the difference of subject device with predicate device does not raise different questions of safety and effectiveness.</p> |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                                            | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                                                                                                         | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <p>Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.</p> <p><b>(note: Nasal Cannula is not included in the JM-P50A package and 510k application scope.)</b></p> | <p>Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.</p>                                                                                                                                           | <p>Same</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                | <p>Battery- utilizes an 8-cell lithium battery</p> <p>Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.</p>                                          | <p>Battery – utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the concentrator.</p> <p>Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.</p> | <p>Similar</p> <p>Both of subject device and predicate device include 8-cell lithium battery, and the same method to attach battery, but the predicate device includes 16-cell battery also.</p> <p>Meanwhile, the 8-cell battery of the subject device has been testing as per IEC 62133-2:2017, and IEC 60601-1 clause 15.4.3 to prevent incorrect connection of polarity, prevented battery overcharging as well as RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire.</p> <p>Therefore, the difference of</p> |

| SE Comparisons                | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Discussion of difference                                                                             |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | subject device with predicate device does not raise different questions of safety and effectiveness. |
| <b>Principle of Operation</b> | <p>The Jumao JM-P50A Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an air tank. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function.</p> <p>Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Jumao JM-P50A Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.</p> | <p>The Inogen Rove 6 Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function.</p> <p>Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Inogen Rove 6 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.</p> | Same                                                                                                 |
| <b>Performance</b>            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                      |

| SE Comparisons                                          | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |           |           |           |           |           |                                                         | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6) |           |           |           |           |           |           | Discussion of difference |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|-----------|-----------|---------------------------------------------------------|----------------------------------------------------------------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|--------------------------|------|------|------|------|-------|-------|----|------|------|------|------|------|------|----|------|------|------|------|------|------|----|-----|------|------|------|------|------|----|-----|------|------|------|------|------|----|-----|------|------|------|------|------|----|------|------|-------|------|------|------|---------------------------------|-----|-----|-----|----|------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|--|--------------------|-----------|-----------|-----------|-----------|-----------|-----------|----|------|------|------|------|-------|-------|----|------|------|------|------|------|------|----|------|------|------|------|------|------|----|-----|------|------|------|------|------|----|-----|------|------|------|------|------|----|-----|------|------|------|------|------|----|------|------|-------|------|------|------|---------------------------------|-----|-----|-----|----|------|------|------|--|--|--|--|--|--|
| Oxygen Delivery Mode                                    | Pulse Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |           |           |           |           |           |                                                         | Pulse Dose                                                                             |           |           |           |           |           |           | Same                     |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| Flow control settings                                   | Pulse dose setting 1,2,3,4,5,6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |           |           |           |           |           |                                                         | Pulse dose setting 1,2,3,4,5,6                                                         |           |           |           |           |           |           | Same                     |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| Output Flow                                             | <table><tr><td>BREATHS PER MINUTE</td><td>Setting 1</td><td>Setting 2</td><td>Setting 3</td><td>Setting 4</td><td>Setting 5</td><td>Setting 6</td></tr><tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td></tr><tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>70.0</td><td>84.0</td></tr><tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td><td>52.5</td><td>63.0</td></tr><tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>42.0</td><td>50.4</td></tr><tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>35.0</td><td>42.0</td></tr><tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>30.0</td><td>36.0</td></tr><tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>26.3</td><td>31.5</td></tr><tr><td>Total volume Per minute(ml/min)</td><td>210</td><td>420</td><td>630</td><td>84</td><td>1050</td><td>1260</td></tr></table> |           |           |           |           |           |                                                         | BREATHS PER MINUTE                                                                     | Setting 1 | Setting 2 | Setting 3 | Setting 4 | Setting 5 | Setting 6 | 10                       | 21.0 | 42.0 | 63.0 | 84.0 | 105.0 | 126.0 | 15 | 14.0 | 28.0 | 42.0 | 56.0 | 70.0 | 84.0 | 20 | 10.5 | 21.0 | 31.5 | 42.0 | 52.5 | 63.0 | 25 | 8.4 | 16.8 | 25.2 | 33.6 | 42.0 | 50.4 | 30 | 7.0 | 14.0 | 21.0 | 28.0 | 35.0 | 42.0 | 35 | 6.0 | 12.0 | 18.0 | 24.0 | 30.0 | 36.0 | 40 | 5.25 | 10.5 | 15.75 | 21.0 | 26.3 | 31.5 | Total volume Per minute(ml/min) | 210 | 420 | 630 | 84 | 1050 | 1260 | <table><tr><td>BREATHS PER MINUTE</td><td>Setting 1</td><td>Setting 2</td><td>Setting 3</td><td>Setting 4</td><td>Setting 5</td><td>Setting 6</td></tr><tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td></tr><tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>70.0</td><td>84.0</td></tr><tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td><td>52.5</td><td>63.0</td></tr><tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>42.0</td><td>50.4</td></tr><tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>35.0</td><td>42.0</td></tr><tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>30.0</td><td>36.0</td></tr><tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>26.3</td><td>31.5</td></tr><tr><td>Total volume Per minute(ml/min)</td><td>210</td><td>420</td><td>630</td><td>84</td><td>1050</td><td>1260</td></tr></table> |  |  |  |  |  |  | BREATHS PER MINUTE | Setting 1 | Setting 2 | Setting 3 | Setting 4 | Setting 5 | Setting 6 | 10 | 21.0 | 42.0 | 63.0 | 84.0 | 105.0 | 126.0 | 15 | 14.0 | 28.0 | 42.0 | 56.0 | 70.0 | 84.0 | 20 | 10.5 | 21.0 | 31.5 | 42.0 | 52.5 | 63.0 | 25 | 8.4 | 16.8 | 25.2 | 33.6 | 42.0 | 50.4 | 30 | 7.0 | 14.0 | 21.0 | 28.0 | 35.0 | 42.0 | 35 | 6.0 | 12.0 | 18.0 | 24.0 | 30.0 | 36.0 | 40 | 5.25 | 10.5 | 15.75 | 21.0 | 26.3 | 31.5 | Total volume Per minute(ml/min) | 210 | 420 | 630 | 84 | 1050 | 1260 | Same |  |  |  |  |  |  |
|                                                         | BREATHS PER MINUTE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Setting 1 | Setting 2 | Setting 3 | Setting 4 | Setting 5 | Setting 6                                               |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 21.0      | 42.0      | 63.0      | 84.0      | 105.0     | 126.0                                                   |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 15                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 14.0      | 28.0      | 42.0      | 56.0      | 70.0      | 84.0                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 20                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 10.5      | 21.0      | 31.5      | 42.0      | 52.5      | 63.0                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 25                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 8.4       | 16.8      | 25.2      | 33.6      | 42.0      | 50.4                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 30                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 7.0       | 14.0      | 21.0      | 28.0      | 35.0      | 42.0                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 35                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 6.0       | 12.0      | 18.0      | 24.0      | 30.0      | 36.0                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | 40                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 5.25      | 10.5      | 15.75     | 21.0      | 26.3      | 31.5                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
|                                                         | Total volume Per minute(ml/min)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 210       | 420       | 630       | 84        | 1050      | 1260                                                    |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| BREATHS PER MINUTE                                      | Setting 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Setting 2 | Setting 3 | Setting 4 | Setting 5 | Setting 6 |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 10                                                      | 21.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 42.0      | 63.0      | 84.0      | 105.0     | 126.0     |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 15                                                      | 14.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 28.0      | 42.0      | 56.0      | 70.0      | 84.0      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 20                                                      | 10.5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 21.0      | 31.5      | 42.0      | 52.5      | 63.0      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 25                                                      | 8.4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 16.8      | 25.2      | 33.6      | 42.0      | 50.4      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 30                                                      | 7.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 14.0      | 21.0      | 28.0      | 35.0      | 42.0      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 35                                                      | 6.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 12.0      | 18.0      | 24.0      | 30.0      | 36.0      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| 40                                                      | 5.25                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 10.5      | 15.75     | 21.0      | 26.3      | 31.5      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| Total volume Per minute(ml/min)                         | 210                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 420       | 630       | 84        | 1050      | 1260      |                                                         |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| Per ISO 80601-2-67 +/- 15% over all operation condition |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |           |           |           |           |           | Per ISO 80601-2-67 +/- 15% over all operation condition |                                                                                        |           |           |           |           |           |           |                          |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| Oxygen Purity                                           | 90% - 3%/+6% at all settings                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |           |           |           |           |           |                                                         | 90% - 3%/+6% at all settings                                                           |           |           |           |           |           |           | Same                     |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |
| Maximum Outlet Pressure                                 | <199 kPa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |           |           |           |           |           |                                                         | <199 kPa                                                                               |           |           |           |           |           |           | Same                     |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |  |                    |           |           |           |           |           |           |    |      |      |      |      |       |       |    |      |      |      |      |      |      |    |      |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |     |      |      |      |      |      |    |      |      |       |      |      |      |                                 |     |     |     |    |      |      |      |  |  |  |  |  |  |

| SE Comparisons                  | Subject device<br>(Portable Oxygen Concentrator,<br>model: JM-P50A)                                            | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model:<br>INOGEN ROVE 6)           | Discussion of difference                                                                                                                                                                                               |
|---------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inspiratory trigger sensitivity | < 0.12 cm H2O                                                                                                  | < 0.12 cmH2O                                                                                        | Same                                                                                                                                                                                                                   |
| Warm up time                    | 2 minutes                                                                                                      | 2 minutes                                                                                           | Same                                                                                                                                                                                                                   |
| Acoustic Noise                  | 43 dBA typical at setting 2<br>Maximum system sound pressure of 61 dBA<br>Maximum system sound power of 66 dBA | 39 dBA at setting 2<br>Maximum system sound pressure of 54 dBA Maximum system sound power of 62 dBA | Similar with the predicate device<br>The Acoustic Noise of subject device JM-P50A is 61 dBA on maximum setting (at 1.26LPM), which is a little higher than 54 dBA on maximum setting (at 1.26LPM) of predicate device. |

| SE Comparisons                               | Subject device<br>(Portable Oxygen Concentrator,<br>model: JM-P50A)                                                                                                                                                                                                                                                                                                                                           | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model:<br>INOGEN ROVE 6)                                                                                                                                                                           | Discussion of difference                                                                                                                                                                                                                                               |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                              |                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                     | Therefore, the acoustic noise of subject device does not raise different questions of safety and effectiveness.                                                                                                                                                        |
| <b>Performance Standards</b>                 |                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| <b>Performance Electrical Safety and EMC</b> | <ul style="list-style-type: none"> <li>ANSI AAMI ES60601-1:2005/(R)2012 &amp; A1:2012, C1:2009/(R)2012 &amp; A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]</li> <li>IEC 60601-1-2:2020</li> <li>IEC 60601-1-8:2020</li> <li>IEC 60601-1-11:2020</li> <li>ISO 80601-2-69:2020</li> <li>ISO 80601-2-67:2020</li> <li>IEC 62133-2:2017</li> <li>IEC 60601-1-6:2020</li> <li>IEC 62366-1:2005+A2:2020</li> </ul> | <ul style="list-style-type: none"> <li>IEC 60601-1:2012</li> <li>IEC 60601-1-2: 2012</li> <li>IEC 60601-1-6:2020</li> <li>IEC 60601-1-8:2012</li> <li>IEC 60601-1-11:2015</li> <li>ISO 80601-2-69:2020</li> <li>ISO 80601-2-67:2020</li> <li>IEC 62366-1</li> </ul> | <p>Same</p> <p>The subject device meets the new version of ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-1-6 and IEC 62366-1. The lithium battery of subject meets the requirement of IEC 62133-2: 2017. The performance of subject</p> |

| SE Comparisons               | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                           | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                                                                                                                                                                                                                              | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                              |                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                     | device including Oxygen Purity, Maximum Outlet Pressure, Inspiratory trigger sensitivity is same with Predicate device. Therefore, the acoustic noise of subject device does not raise different questions of safety and effectiveness.                                                                                                                                                                                                                                                                           |
| <b>Communications</b>        |                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Power / Energy Source</b> | <p>AC/DC Power Adapter – Utilizes 100-240V, 50-60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.</p> <p>Battery – utilizes an 8-cell lithium battery.</p> | <p>AC/DC Power Adapter – Utilizes 100-240V, 50-60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.</p> <p>DC Power Cable – cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator.</p> <p>Battery – utilizes an 8 or 16-cell lithium battery.</p> | <p>Similar with the predicate device</p> <p>The subject device does not come with a DC power cable. Instead, it is equipped with an AC adapter and 8-cell lithium Battery as the power source. The AC adapter can convert AC power to DC power for the device's power supply and battery charging.</p> <p>As well as the use environment of subject device is the home or a professional healthcare facility.</p> <p>Therefore, the difference of subject device with predicate device do not raise different</p> |

| SE Comparisons             | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)                                                                                                                        | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            |                                                                                                 |                                                                                                                                                                                                               | questions of safety and effectiveness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Power requirements:</b> | AC power:<br>100-240VA.C., 50-60 Hz, 2.0-1.0A<br><br>Battery powered: 14.8V D.C., 6.4A, 94.72Wh | AC power:<br>100 to 240 VAC, 50 to 60 Hz<br>Autosensing 2.0 - 1.0A<br><br>DC Power:<br>13.5-15.0, 24 VDC, 120W<br>Max voltage: 12.0 to 16.8 VDC( $\pm 0.5$ )<br><br>Battery powered: 12.0 to 16.8 VDC (+ 0.5) | <p>Similar with the predicate device</p> <p>The power requirement of subject device is the same with predicate device.</p> <p>The subject device does not come with a DC power cable. The subject device is equipped with an AC adapter and 8-cell lithium Battery as the power source. The AC adapter can convert AC power to DC power for the device's power supply and battery charging.</p> <p>As well as the use environment of subject device is limited within the home and professional healthcare facilities.</p> <p>The battery power of subject device is smaller than predicate device. The battery of the subject device is only used by itself. And the subject device can be work normal and the</p> |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A) | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6) | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------|------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                |                                                                  |                                                                                        | <p>performance including Oxygen Purity (87%-96%), Maximum Outlet Pressure (less than 199kPa) meet and meet requirement as per clause of 201.12.1.103 and 201.12.1.104 of ISO 80601-2-69 as well as the Inspiratory trigger sensitivity (less than 0.12mH2O) and delivered oxygen volume have been test and meet as per clause 201.12.1.101 ISO 80601-2-67 under battery power.</p> <p>Meanwhile, when the battery of subject is low capacity will trigger the Low Battery alarm (battery capacity less 10%) or low battery shutdown alarm (battery capacity less than 5%). Furthermore, the alarm condition of the subject has been tested and meet as per clause 201.11.8.101.2 of ISO 80601-2-69 provided in this submission.</p> <p>Therefore, the difference does not raise different questions of safety and effectiveness.</p> |

| SE Comparisons         | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                          | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6)       | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Battery re-charge time | <p>1) Not more than 5 hours when the device is operating and plugged into AC power.</p> <p>2) Not more than 3 hours when the device is off and plugged into AC power.</p> | <p>Standard (BA-500 &amp; BA-508): up to 3 hours</p> <p>Extended (BA-516): up to 4 hours</p> | <p>Similar with the predicate device</p> <p>The Predicate device do not specify the product status corresponding to the product charging time. When subject device is off, the charging time is the same with the of standard battery predicate device.</p> <p>When the device is switched on, the charging time of the predicated is not public. In working condition, the subject device can be charged for no more than five hours. Alternatively, the user can contact JUMAO or JUMAO 's distributors to purchase a battery of the same specification for spare or choose to charge it in the switch-off condition. Accordingly, the discrepancy in charging times under operational power conditions does not impact product functionality. Furthermore, the product's charging time has been validated in the attachment "009_Charge-discharge Report_20240730".</p> <p>Therefore, the difference does not raise different questions of safety</p> |

| SE Comparisons                         | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6) | Discussion of difference                                                                                                                                               |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                        | and effectiveness.                                                                                                                                                     |
| Material of Patient contact components | <p>Materials of directly contacted components: Enclosure : PC+ABS<br/>Button: PET</p> <p>Materials of indirectly contacted components (gas pathway material):<br/>Particle filter: Stainless Steel, ABS<br/>Inlet Filter: Chemical fiber<br/>Air Compressor: PTFE<br/>Sieve Beds: ABS, Synthetic Zeolite<br/>3-way valve manifold, 2-way valve manifold: Silica gel, PU<br/>3-way valve, 2-way valve: Silicone rubber<br/>Pressure Sensor: Silica gel<br/>Muffler: PE<br/>Oxygen Concentration Sensor: ABS<br/>Air Tank: ABS<br/>Respiratory Sensor: Fluorine rubber<br/>Outlet Filter: PP<br/>Outlet Nozzle: Silica gel, ABS, Aluminum alloy</p> | Not public                                                                             | <p>Different</p> <p>The material of predicate device is not public.</p> <p>The material used in the subject device are commonly used materials in medical devices.</p> |

| SE Comparisons               | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A)                                       | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6) | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                              |                                                                                                        |                                                                                        | <p>As well as the subject device has been testing as per the ISO 18562-2, ISO 18562-3 and permanent duration (&gt;30 days), furthermore, based on the evaluation result as per the ISO 18562-1, the PM2.5 and PM10 meet the ISO 18562-1 and the VOC released from the subject device are unlikely to result in toxicological effects.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p> |
| Duration and type of contact | Type of indirectly contact material(pathway): externally communicating, gas pathway contacting devices | Type of contact: Externally Communicating, Tissue                                      | <p><b>Same</b></p> <p>The gas pathway material has been testing as per the ISO 18562-2, ISO 18562-3 and permanent duration (&gt;30 days),</p> <p>Therefore, the difference of</p>                                                                                                                                                                                                                                                                                                |

| SE Comparisons        | Subject device<br>(Portable Oxygen Concentrator,<br>model: JM-P50A)                                                                                                                        | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model:<br>INOGEN ROVE 6)        | Discussion of difference                                                                                                                                                                                                                          |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                                                                                                                                                                                            |                                                                                                  | subject device with predicate device do not raise different questions of safety and effectiveness.                                                                                                                                                |
|                       | Duration of duration: Permanent Duration (>30 days)                                                                                                                                        | Duration of duration: Permanent Duration (>30 days)                                              | <b>Same</b>                                                                                                                                                                                                                                       |
| Biocompatibility      | Direct Contacting Materials:<br><br>Shell: PC+ABS<br>Control Panel: PET                                                                                                                    | Not public                                                                                       | Different<br><br>The materials of the shell and control panel are commonly used patient contact materials.<br><br>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness. |
|                       | For the indirectly contact material(pathway) have been test according to below:<br>ISO 18562-2: 2017 Particulate matter<br>ISO 18562-3:2017 Volatile organic compounds<br>ISO 18562-1:2024 | ISO 18562-2: 2017 Particulate matter<br>ISO 18562-3:2017 Volatile organic compounds              | <b>Same</b>                                                                                                                                                                                                                                       |
| Operating Environment | Operating temperature: 41 to 104°F (5 to 40°C)<br>Operating humidity: 15% to 90%, non-condensing<br><br>Operating altitude: 70kPa to 106 kPa                                               | Operating temperature: 41 to 104°F (5 to 40°C)<br>Operating humidity: 15% to 90%, non-condensing | <b>Same</b>                                                                                                                                                                                                                                       |

| SE Comparisons                | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A) | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6) | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               | (0 - 10,000 ft (0 - 3048 m)                                      | Operating altitude: 0 to 10,000 ft (0 to 3048 meters)                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Shipping and Storage humidity | 10% to 90% non-condensing Store in a dry environment             | Up to 90%, non-condensing<br>Store in a dry environment.                               | <p>Similar with the predicate device</p> <p>The shipping and storage humidity condition of the subject device have been described in the User manual and Outer package drawing.</p> <p>Both the subject device and the predicted device have the same upper limit for humidity conditions, but there are slight differences in the lower limit.</p> <p>Meanwhile, the subject device have been tested in according to the clause 4.2.2 IEC 60601-1-11 under the 10% to 90% non-condensing and the result shows the performance including Oxygen Purity (87%-96%), Maximum Outlet Pressure (less than 199kPa) meet and meet requirement as per clause of 201.12.1.103 and 201.12.1.104 of ISO 80601-2-69 as well as the Inspiratory trigger sensitivity (less than 0.12mH2O) and delivered oxygen volume have been test and meet as per clause 201.12.1.101 ISO</p> |

| SE Comparisons                   | Subject device<br>(Portable Oxygen Concentrator, model: JM-P50A) | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6) | Discussion of difference                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  |                                                                  |                                                                                        | <p>80601-2-67.</p> <p>Therefore, the difference of subject device with predicate device do not raise different questions of safety and effectiveness.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Shipping and storage temperature | - 20 °C to 60 °C (-4 °F to 140 °F)                               | -25 to 70°C ( -13 to 158°F)                                                            | <p>Similar with the predicate</p> <p>The shipping and storage temperature condition is within the range of the predicate device, and the subject device have been tested in according to the clause 4.2.2 IEC 60601-1-11 under the -20°C to 60 °C (-4 °F to 140 °F) and the result shows the performance including Oxygen Purity (87%-96%), Maximum Outlet Pressure (less than 199kPa) test and meet requirement as per clause of 201.12.1.103 and 201.12.1.104 of ISO 80601-2-69 as well as the Inspiratory trigger sensitivity (less than 0.12mH2O) and delivered oxygen volume have been test and meet as per clause 201.12.1.101 ISO 80601-2-67.</p> <p>Therefore, the difference of subject device with predicate</p> |

| SE Comparisons | Subject device<br>(Portable Oxygen Concentrator,<br>model: JM-P50A) | Predicate Device<br>(Inogen Rove 6 Portable Oxygen Concentrator, Model:<br>INOGEN ROVE 6) | Discussion of difference                                             |
|----------------|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
|                |                                                                     |                                                                                           | device do not raise different questions of safety and effectiveness. |

## 8. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, ISO 80601-2-69: 2020 and ISO 80601-2-67: 2020 for performance and IEC 62304 for software verification are complied. See below table for details:

| Standards                                                                                                                | Standards Name                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ANSI AAMI<br>ES60601-1:2005/(R)2012 &<br>A1:2012, C1:2009/(R)2012<br>& A2:2010/(R)2012 (Cons.<br>Text) [Incl. AMD2:2021] | Medical Electrical Equipment - Part 1: General<br>Requirements For Basic Safety And Essential<br>Performance                                                                                                                                                             |
| IEC 60601-1-2 Edition 4.1<br>2020-09 CONSOLIDATED<br>VERSION                                                             | Medical Electrical Equipment -- Part 1-2: General<br>Requirements For Basic Safety And Essential<br>Performance -- Collateral Standard: Electromagnetic<br>Disturbances -- Requirements And Tests                                                                        |
| IEC 60601-1-11 Edition 2.1<br>2020-07 CONSOLIDATED<br>VERSION                                                            | Medical Electrical Equipment - Part 1-2: General<br>Requirements For Basic Safety And Essential<br>Performance - Collateral Standard: Electromagnetic<br>Disturbances - Requirements And Tests                                                                           |
| IEC 60601-1-8 Edition 2.2<br>2020-07 CONSOLIDATED<br>VERSION                                                             | Medical electrical equipment - Part 1-8: General<br>requirements for basic safety and essential<br>performance - Collateral Standard: General<br>requirements, tests and guidance for alarm systems in<br>medical electrical equipment and medical electrical<br>systems |
| IEC<br>60601-1-6:2005/AMD2:2020                                                                                          | Medical electrical equipment - Part 1-6:General<br>requirements for basic safety and essential<br>performance -Collateral standard: Usability                                                                                                                            |
| ISO 80601-2-69: 2020                                                                                                     | Medical electrical equipment. Particular requirements<br>for the basic safety and essential performance of<br>oxygen concentrator equipment                                                                                                                              |
| ISO 80601-2-67: 2020                                                                                                     | Medical electrical equipment. Particular requirements<br>for basic safety and essential performance of<br>oxygen-conserving equipment                                                                                                                                    |
| ISO 18562-1:2024                                                                                                         | Biocompatibility evaluation of breathing gas pathways<br>in healthcare applications<br>Part 1: Evaluation and testing within a risk<br>management process                                                                                                                |

|                        |                                                                                                                                                                                                                                          |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 18562-2: 2017      | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of particulate matter                                                                                                     |
| ISO 18562-3: 2017      | Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of volatile organic compounds (VOCs)                                                                                               |
| IEC 62133-2: 2017      | Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems |
| ISO 10993-17:2023      | Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents                                                                                                                         |
| IEC 62304:2006+A1:2015 | Medical device software - Software life cycle processes                                                                                                                                                                                  |

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Device Software Functions - Guidance for Industry and FDA Staff, June 2023.

## 9. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

## 10. Conclusions

The Portable Oxygen Concentrator, model: JM-P50A, has the same intended use and similar characteristics as the cleared device Inogen Rove 6 Portable Oxygen Concentrator, Model: INOGEN ROVE 6.

Moreover, The Portable Oxygen Concentrator, model: JM-P50A meets safety and performance standards required for portable oxygen concentrators verified through testing, and bench testing contained in this submission supplied demonstrate that the differences existed between JM-P50A and INOGEN ROVE 6 do not raise any different questions of safety or effectiveness.

Thus, the Portable Oxygen Concentrator, model: JM-P50A is Substantially Equivalent (SE) to the predicate device.